

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

NOVO NORDISK A/S and NOVO NORDISK,
INC.,

Plaintiffs, CIVIL CASE NO. 05-40188

v.

CARACO PHARMACEUTICAL
LABORATORIES, LTD. and SUN
PHARMACEUTICAL INDUSTRIES, LTD.,

HONORABLE PAUL V. GADOLA
U.S. DISTRICT COURT

Defendants.

ORDER DENYING DEFENDANT SUN'S MOTION TO DISMISS

Plaintiffs Novo Nordisk A/S and Novo Nordisk Inc. first filed suit against Defendant Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") on June 9, 2005. After receiving leave from the Court, Novo Nordisk filed an Amended Complaint on September 14, 2005, adding Defendant Sun Pharmaceuticals Industries, Ltd. ("Sun") as a party to the action. Defendant Sun filed a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) on October 3, 2005, arguing that Plaintiffs had failed to state a claim upon which relief could be granted against Sun. After all briefings had been submitted by both parties, oral arguments were presented before this Court. For the reasons set out below, the Court denies Defendant Sun's motion.

I. Background

This is a patent infringement action under the Patent Act, 35 U.S.C. § 271 *et seq.* In 1984, Congress adopted the Hatch-Waxman Act (codified at 21 U.S.C. §§ 355 and 360, 35 U.S.C. §§ 156 and 271), which "address[ed] the need to bring generic drugs to the market quickly and changed the

way in which the Food and Drug Administration (FDA) approved the manufacture and use of new and generic drugs.” *Alcon Labs., Inc. v. Allergan, Inc.*, 256 F. Supp. 2d 1080, 1081 (C.D. Cal. 2003). Under the Hatch-Waxman Act, after a party files an Abbreviated New Drug Application (“ANDA”) with the FDA seeking FDA approval for a generic version of a drug, another party can challenge the application as a patent infringement before the applied-for drug is created or marketed.

In this case, Plaintiff Novo Nordisk A/S is a Danish company which owns United States Patent No. 6,677,358 (“the ‘358 patent”). The ‘358 patent involves a pharmaceutical composition and method of treatment for Non-Insulin Dependent Diabetes Mellitus. The claims in the ‘358 patent require the drug repaglinide, which is marketed by Plaintiffs. Defendant Caraco is a Michigan corporation that filed an Abbreviated New Drug Application (“ANDA”) with the FDA seeking FDA approval to market a generic version of repaglinide. Alleging that by filing the ANDA, it had infringed upon Plaintiffs’ ‘358 patent, Plaintiffs began this cause of action against Caraco. Sun was later added as a defendant through Plaintiffs’ motion to amend.

Defendant Sun is a majority shareholder of Caraco. Plaintiffs argue that Sun is properly a defendant in this action because it is the parent company of Caraco and because it controls and directs Caraco’s operations. Plaintiffs assert two claims against Defendants: 1) direct infringement in violation of 35 U.S.C. § 271(e)(2); and 2) active inducement of infringement in violation of 35 U.S.C. § 271(b). Defendant Sun now brings this motion to dismiss, arguing that because it did not file the ANDA, Plaintiffs’ claims against Sun fail as a matter of law.

II. Legal Standard

Federal Rule of Civil Procedure 12(b)(6) authorizes the district courts to dismiss any complaint that fails “to state a claim upon which relief can be granted.” Rule 12(b)(6) allows a

defendant to test whether, as a matter of law, the plaintiff is entitled to legal relief even if everything alleged in the complaint is true. *See Minger v. Green*, 239 F.3d 793, 797 (6th Cir. 2001) (citations omitted). In applying the standards under Rule 12(b)(6), the Court must presume all well-pleaded factual allegations in the complaint to be true and draw all reasonable inferences from those allegations in favor of the non-moving party. *Mayer v. Mylod*, 988 F.2d 635, 638 (6th Cir. 1993).

The Court will not, however, presume the truthfulness of any legal conclusion, opinion, or deduction, even if it is couched as a factual allegation. *Morgan v. Church's Fried Chicken*, 829 F.2d 10, 12 (6th Cir. 1987). The Court will not dismiss a cause of action “for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.” *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957). Although the pleading standard is liberal, bald assertions and conclusions of law will not enable a complaint to survive a motion pursuant to Rule 12(b)(6). *Leeds v. Meltz*, 85 F.3d 51, 53 (2d Cir. 1996). To determine whether Plaintiff has stated a claim, the Court will examine the complaint and any written instruments that are attached as exhibits to the pleading. Fed. R. Civ. P. 12(b)(6) & 10(c).

III. Analysis

1. Direct Infringement

In its motion, Defendant Sun argues that because Sun did not file the ANDA, Sun cannot be liable for direct infringement. In response, Plaintiffs argue that, as the parent company of Caraco, Sun can be found liable through a “piercing the corporate veil” agency theory.

The relevant statutory language of the Hatch-Waxman Act creating a claim of direct infringement for filing an ANDA states:

(2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 USCS § 355(j)] or described in section 505(b)(2) of such Act [21 USCS § 355(b)(2)] for a drug claimed in a patent or the use of which is claimed in a patent . . .

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2).

The plain language of the statute appears to indicate that only the entity submitting the application can be found liable: “It shall be an act of infringement to submit . . . an application . . .” 35 U.S.C. § 271(e)(2)(A). This interpretation of the statute is confirmed by recent caselaw. The Court of Appeals for the Federal Circuit stated in *Warner-Lambert Co. v. Apotex Corp.* that § 271(e)(2) “explicitly defines the act of infringement as the filing of the ANDA.” *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003); *see also Smithkline Beecham Corp. v. Geneva Pharm., Inc.*, 287 F. Supp. 2d 576, 585 (E.D. Pa. 2002) (citation omitted) (“Section 271(e)(2)(A) unambiguously refers only to persons who submit ANDAs.”).

In the instant case, it is undisputed that Caraco, and not Sun, is the entity that submitted the ANDA. Plaintiffs argue, however, that Sun can still be found liable for submitting the ANDA under a “piercing the corporate veil” agency theory. In support, Plaintiffs argue that as the parent corporation to Caraco, Sun directed, controlled, and participated in the submission of ANDA, and stands to directly benefit should the ANDA be granted.

Generally, parent and subsidiary corporations are presumed to be separate and distinct legal entities. *Seasword v. Hilti, Inc.*, 537 N.W.2d 221, 224 (Mich. 1995). This presumption, sometimes called “the corporate veil,” may be pierced in the interests of justice or other overriding public

policy. *See id.* In order to “pierce the corporate veil” and to state a claim “based on an alleged parent-subsidary relationship, a plaintiff would have to allege: (1) the existence of a parent-subsidary relationship, and (2) facts that justify piercing the corporate veil.” *Id.* Some facts that justify piercing the corporate veil are facts showing the existence of an agency relationship between the entities where the parent effectively controls the conduct of the subsidiary. *See Tegal Corp. v. Tokyo Electron Co., Ltd.*, 248 F.3d 1376, 1379 (Fed. Cir. 2001), *A. Stucki Co. v. Worthington Indus., Inc.*, 849 F.2d 593, 596 (Fed. Cir. 1988). Plaintiffs argue that its allegations are sufficient to establish a “piercing the corporate veil” theory, while Defendant disagrees.

Plaintiffs’ claims as pleaded in the Amended Complaint are governed by the standard set forth in Federal Rule of Civil Procedure 8(a). Under Rule 8(a), a complaint is adequate when it contains “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a)(2); *see Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 512 (2002). “Such a statement must simply ‘give the defendant fair notice of what the plaintiff’s claim is and the grounds upon which it rests.’” *Swierkiewicz*, 534 at 512 (citing *Conley v. Gibson*, 355 U.S. 41, 47 (1957)).

In this case, the Court finds that the liberal pleading standard of Rule 8(a) governs. Plaintiffs have first alleged that Sun and Caraco have a parent-subsidary relationship. More importantly, Plaintiffs have alleged that Sun directed and controlled the filing of the ANDA, and that Sun stands to benefit from the ANDA. *See Am. Comp.*, parag. 15 (Sept. 14, 2005) (“Upon information and belief, Sun directed, controlled and/or participated in the filing of the ANDA and stands to benefit directly should the ANDA be granted.”).

Because of the liberal pleading standard of Rule 8(a) and the presumption in favor of the

non-moving party's allegations of a Rule 12(b)(6) motion, this Court is compelled to find that Plaintiffs have sufficiently alleged facts that could justify piercing the corporate veil between Caraco and Sun. Plaintiffs have made allegations that Sun effectively controls the actions of its subsidiary, Caraco, and directed Caraco to submit the ANDA. These allegations have given Defendants fair notice of Plaintiffs' "piercing the corporate veil" agency theory. Whether this alleged controlling parent-subsiary relationship exists in actuality is a matter better left up to the discovery process.

2. Active Inducement of Infringement

In their complaint, Plaintiffs also allege that Defendants are actively inducing the infringement of the '358 patent, in violation of 35 U.S.C. § 271(b). *See* Am. Comp., para. 22 (Sept. 14, 2005) ("Upon information and belief, upon approval of its ANDA, Defendants will actively solicit others to use, offer for sale, or sell in the U.S., the repaglinide products that are the subject of the ANDA alone and with metformin and to use such combination in the treatment of NIDDM. Such activities by Defendants will actively induce infringement of at least one of the claims of the '358 patent under Title 35, United States Code, § 271(b)."). Section 271(b) states: "Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). Sun argues that a claim for active inducement of infringement can only be brought against the ANDA applicant. Sun argues, therefore, that since it is not the applicant for the ANDA, it cannot be held liable for active inducement of infringement.

The Court of Appeals for the Federal Circuit has recognized that a claim for active inducement of infringement against an ANDA applicant premised on § 271(e)(2) is legally cognizable. *See Allergan, Inc. v. Alcon Labs.*, 324 F.3d 1322, 1330 (Fed. Cir. 2003). The Federal Circuit has not directly answered the question as to whether an entity which did not file the ANDA

can be liable for inducement of infringement under § 271(e)(2). District courts considering the issue have ruled in different ways. *Compare Smithkline Beecham Corp. v. Geneva Pharms.*, 287 F. Supp. 2d 576 (E.D. Pa. 2002) and *Smithkline Beecham Corp. v. Pentech Pharms., Inc.*, No. 00 C 2855, 2001 WL 184804 (N.D. Ill. Feb. 20, 2001) (cases finding a cause of action for inducement of infringement against entities that did not file an ANDA), with *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 321 F. Supp. 2d 612 (D. Del. 2004) and *AstraZeneca AB v. Mylan Labs., Inc.*, 265 F. Supp. 2d 213 (S.D.N.Y. 2003) (cases finding no cause of action for inducement of infringement premised against entities which had not filed an ANDA even though they encouraged or facilitated the ANDA filing).

The Court declines to resolve this question because, as has been discussed in the previous section of this order, due to the liberal pleading standard of Rule 8(a) and the Rule 12(b)(6) presumption in favor of the non-moving party, Plaintiffs have sufficiently alleged a “piercing of the corporate veil” agency theory against Sun, by alleging Sun’s extensive control over Caraco in a parent-subsiary relationship. Accordingly, taking all reasonable inferences from the allegations in favor of Plaintiffs, the Court finds that Plaintiffs’ allegations are sufficient to state a cause of action for inducement of infringement against Sun.

IV. Conclusion

At the Rule 12(b)(6) stage of litigation, allegations and reasonable inferences therefrom must be taken in favor of Plaintiffs. Moreover, Rule 8(b) requires the Court to take a liberal stand when considering pleadings. In this case, the pleadings have sufficiently put Defendants on notice of the “piercing the corporate veil” agency theory. Whether in actuality Sun exerts the extensive dominion and control over Caraco alleged by Plaintiffs is a matter to be pursued through discovery. It is, however, inappropriate to dismiss Sun at this early stage in litigation.

ACCORDINGLY, IT IS HEREBY ORDERED that Defendant's motion to dismiss [docket entry 24] is **DENIED**.

SO ORDERED.

Dated: September 20, 2006

s/Paul V. Gadola
HONORABLE PAUL V. GADOLA
UNITED STATES DISTRICT JUDGE

Certificate of Service

I hereby certify that on September 21, 2006, I electronically filed the foregoing paper with the Clerk of the Court using the ECF system which will send notification of such filing to the following:

Eric S. Goldsmith; James F. Hunt; Robert C. Sullivan, Jr.; Morley Witus, and I hereby certify that I have mailed by United States Postal Service the paper to the following non-ECF participants: _____.

s/Ruth A. Brissaud
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